

HPV vaccine uptake after introduction of the vaccine in Germany

An analysis of administrative data

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Abbreviations: HPV, human papilloma virus; EMA, European Medicines Agency; y, years; STIKO, German Standing Vaccination Committee (Ständige Impfkommission); SHI, statutory health insurance providers; GePaRD, German Pharmacoeconomic Research Database; EBM, Einheitlicher Bewertungsmaßstab (claim codes for outpatient services and procedures); KV, Kassenärztliche Vereinigung (Regional Association of SHI-Accredited Physicians); HH, Hamburg; NRW, North-Rhine-Westphalia; SN, Saxony; SH, Schleswig-Holstein

In Germany, vaccination against human papilloma virus (HPV) has been recommended by the German Standing Vaccination Committee (STIKO) for girls aged 12–17 years since March 2007. The vaccine is free of charge for this age group. Additionally, some statutory health insurance providers (SHI) offer reimbursement for women aged 18–26 years. Currently available information on the uptake or coverage of HPV vaccination is limited to specific regions, age groups, or study populations.

This report describes the HPV vaccine uptake in 2008 for females aged 12–26 years in Germany on a broad regional level based on data from one large SHI. HPV vaccinations were identified by outpatient codes used for reimbursement of vaccine administration. Vaccine uptake was calculated by dividing the number of females, who received at least one HPV vaccine dose by the number of female insureds in the respective age group. The overall study population consisted of 317 234 females, of whom 77 350 received at least one HPV vaccine dose in 2008. Vaccine uptake was 32.2% in the recommended age group, with a peak age at 14–16 years. In the age group of females aged 18–26 years, where HPV vaccination was not officially recommended by the STIKO, uptake was 12.3%. Vaccine uptake in 2008 reflects an early stage after the recommendation of HPV vaccination in 2007. Future changes in vaccine uptake should be further and more promptly monitored.

Human papillomavirus (HPV) is a sexually transmitted infection that is a necessary (but insufficient) cause of 99% of all cervical cancer cases.¹ Two HPV vaccines are available to reduce the risk of developing malignant lesions. The tetravalent HPV vaccine Gardasil® and the bivalent HPV vaccine Cervarix® were approved by the European Medicines Agency (EMA) in 2006 and 2007, respectively. Both vaccines are licensed for girls aged 9 y and older. In Germany, HPV vaccination has been recommended by the German Standing Vaccination Committee (STIKO) since March 2007 for girls aged 12–17 y, preferably before their first sexual intercourse. Following this recommendation, the vaccine is free of charge for this age group. Additionally, some statutory health insurance providers (SHI) offer full reimbursement in terms of further services also for females aged 18–26 y, for whom the vaccine is licensed but not recommended by the STIKO. The costs of the vaccine are directly covered by the SHI and no upfront payment incurs for the patient.

Since Germany does not hold national immunization registries, alternative approaches are necessary to monitor vaccine uptake and/or vaccination coverage.² Based on data from several surveys, HPV vaccination coverage in Germany with at least one vaccine dose ranged from 12% in females aged 12–20 y to 67% in females aged 18–20 y.^{3–5} In one of these studies, the proportion of girls not knowing, whether they had received the vaccination was shown to be 57%,⁵ suggesting that recall bias might considerably affect the validity of self-reported data in this context.⁶ Vaccination record review (n = 161) including females aged 14–19 y showed an HPV vaccination coverage with all three recommended doses of 41% in the federal state of Berlin.⁷

To our knowledge, no comprehensive and nationwide information on the uptake or coverage of HPV vaccination in Germany is available to date. Administrative claims data from health insurances has been shown to be a useful source of data for the monitoring of vaccination coverage or the uptake of newly

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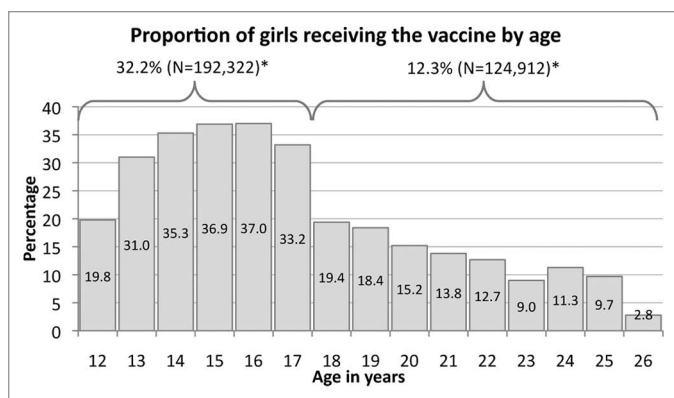


Figure 1. Proportion of girls/women receiving the vaccine in 2008 by age. *Limited to federal states, where vaccination data was available for this age group.

introduced or recommended vaccines.² Against this background, the present (brief) report describes the HPV vaccine uptake in Germany in 2008 for females of all age groups, for whom vaccination was recommended and/or reimbursed (12–26 y) by the health insurance which contributed data to this study. The focus of the study is on the year following the introduction of the HPV vaccine in Germany. While HPV vaccination was recommended by the STIKO in 2007, specific reimbursement codes became widely available in Germany for the first time in 2008 making a comprehensive analysis of the uptake possible.

The study was based on data from one SHI contributing data to the German Pharmacoepidemiological Research Database (GePaRD) which has been described in detail elsewhere.^{8–12} In brief, GePaRD consists of records of 4 SHIs, includes data from more than 17 million insurees of all ages, and covers all geographical regions of Germany. In the present study, 1 of 4 SHIs participated with about 7 million insurees, covering 8.5% of the German population. The database contains data on in- and outpatient diagnoses, diagnostic and therapeutic procedures, and outpatient drug prescriptions. Vaccinations can be identified by specific outpatient codes (Einheitlicher Bewertungsmaßstab, EBM) used for reimbursement of vaccinations. In Germany, utilization of healthcare insurance data for scientific research is regulated by the code of Social Law (§ 75 SGB X). The Federal Ministry of Health and the contributing SHI approved the use of the data for this study. Informed consent was not required by law, since the study was based on pseudonymous data.

Insurees from the federal states of Brandenburg and Hesse were excluded from the present study as no specific EBM codes for the HPV vaccination existed in these federal states during the study period. All female insurees aged 12–26 y, who were continuously insured at the participating SHI between January 1st, 2008 and December 31st, 2008 were included in the study. Vaccine uptake was calculated by dividing the number of girls/women who received at least one dose of HPV vaccine by the number of insurees in the respective age group. For the age group 18–26 y, data from only 4 federal states (Hamburg [HH], North-Rhine-Westphalia [NRW], Saxony [SN], and Schleswig-Holstein [SH]) was considered, since specific EBM codes for

reimbursement of HPV vaccination did not exist for this age group in the other regions. Accordingly, vaccinations were not systematically identifiable for females aged 18–26 y in these other regions and therefore no uptake calculation was possible.

The overall study population consisted of 317 234 females, with 192 322 aged 12–17 y (including all federal states except Hesse and Brandenburg) and 124 912 aged 18–26 y (for the latter considering only the federal states HH, NRW, SN, and SH). A total of 77 350 females received at least one vaccine dose in 2008. In the age group 12–17 y, where vaccination is recommended by the STIKO and reimbursed by the SHIs, 32.2% of the girls received at least one vaccine dose (Fig. 1), with a peak of the proportion at 14–16 y. In females aged 18–26 y, for whom vaccination is not recommended by the STIKO but reimbursement was offered by the SHI providing data, the proportion of vaccinated women was 12.3% in the 4 federal states studied. In these 4 federal states, 45 316 females between 12 and 26 y were vaccinated during the study period. Among these, about two-thirds (66.1%) received the vaccine at the recommended age. Although the vaccination is not recommended for the age of 18–26 y, one-third (33.9%) of the vaccinated females were in this age group.

The present study describes the HPV vaccine uptake in a large study population from 14 out of 16 federal states in Germany in 2008 in females, for whom the vaccination is recommended by the STIKO and from 4 federal states for those women, for whom the vaccine is licensed and reimbursed by the SHI providing data for the study, but no national recommendation currently exists. As assumed, the majority of vaccinated females were in the age group where the vaccination is recommended. This proportion was similar to the one found in a study based on data from private insurance companies in Germany, where 64.7% of the vaccinated females had received the vaccination at the recommended age.¹³ While girls at the lower boundary of the recommended vaccination age have several years to obtain vaccination, the uptake of vaccination of 37% among 16-y-old girls and of 33% among 17-y-old girls in the second year after the recommendation of the vaccine indicates that the acceptance of the vaccine might be too low. This is in line with results from other European countries, where coverage and uptake of the vaccine have been reported below the expected level.^{14,15} In fact, an overview of the HPV vaccination coverage in Europe has shown results ranging from 17% to 81% in the first 2 y after introduction of the vaccine in the respective countries, with the lowest rates in France, Luxemburg, and Norway and the highest in Portugal and the United Kingdom.¹⁵ In the United States, the reported proportion of girls in the age group of 13–17 y who had received at least one vaccine dose ranged from 34.8%¹⁶ in the National Health Interview Survey (NHIS) to 48.7%¹⁷ and 53.8%¹⁸ in the National Immunization Survey-Teen (NIS-Teen) in 2010 and 2012, respectively. In Australia, where a school-based vaccination program has been implemented, the proportion of girls in the seventh grade (~12 y of age) receiving the vaccination has been shown to be about 80% in 2009, 2010, and 2011.^{19–23}

This variation across countries might be due to different implementation approaches (e.g., coverage is higher in countries

with school-based immunization programs such as Australia and the United Kingdom), but also to different methods that are applied to monitor vaccination coverage or uptake.⁶ Previously conducted coverage studies from Germany, which were mainly based on survey data, have shown heterogeneous results, depending on the considered age group, region, and study population.^{3-5,7} Direct comparability of our results with those studies is hampered by different aspects. First of all, an estimation of the vaccination coverage rather than the vaccine uptake was not possible in the context of the present study due to the limited study period (only the year 2008), for which the data was available. For coverage estimations, knowledge about the vaccination status before the study period would have been necessary. Also, the used data refers to a time period shortly after introduction of the vaccine and thus cannot directly depict the situation in more recent years. In fact, sensitivity analyses showed a decrease in the number of administered doses over the year 2008, with the highest numbers in January and the lowest in December. As an example, in NRW the number of administered doses per 100 women ranged from 5.0 in January to 1.1 in December and the same trend could be observed in all regions for which data was available. These observations are in line with sales data provided by Sanofi Pasteur MSD GmbH that indicate a reduction in sold doses of Gardasil® ranging from more than 300 000 doses in January to less than 100 000 doses in December 2008 (data not shown). This might be explained by a post “booming” effect after the introduction of the reimbursement in Germany in March 2007, when especially women in the upper age range of the STIKO recommendation could have been seeking vaccination in a cumulated manner (cohort catch-up). In addition, concerns regarding the HPV vaccination were highly debated in 2008, after the emerging discussion in January about 2 cases of deaths among women who had received HPV vaccination. This is likely to have contributed to the decrease in sold and administered doses. Against this background, vaccine uptake in the following years is likely to be lower than observed in 2008. The reported coverage with at least one dose for different regions in Germany ranged from 12% in girls aged 12–20 y in Bremen (study year 2011) and 67% in females aged 18–20 y in Berlin (study year 2010). These strong differences first underline the observation of a decreasing uptake after a first peak after the introduction of the vaccine and second suggest potential regional differences in HPV vaccination patterns. Stratified analysis of our data also indicated a slightly higher HPV vaccine uptake among persons in the study sample living in eastern as compared with western regions in Germany (data not shown). In a study based on national data from private health insurance companies in Germany, vaccine uptake in 2008 has been reported to be ~12% in females aged 15–18 y.¹³ This presents a much lower estimate of vaccine uptake than the one yielded by our calculations (about 2.5-fold). However, in the other study, not individual but just aggregate data were used and the total number of HPV vaccine administrations per year in each age group was divided by 3 (assuming the receipt of the full immunization series of 3 doses for every girl in that year). Due to the recommended vaccination scheme of 6 mo for completion of the series, most of the girls will not have received all 3 doses

within the same year. Furthermore, the study population of privately insured persons is known to be selective, since only persons with a relatively high annual income have the possibility to join private health insurances. Only about 11% of the population in Germany therefore have private health insurance.²⁴

According to our data, the highest proportion of girls receiving the vaccine was seen between the ages 14–16 y, which was similar to the results from the previously mentioned study based on private insurance data and which has been identified as long-term the most cost-effective age for vaccination in a recent study published by Horn and colleagues.^{13,25} While several countries offer catch-up vaccination programs for females above the recommended vaccination age in order to enhance vaccination coverage also in older females,^{14,20,21,26} no such approach has been chosen in Germany. Comparability of our data with results from countries, where catch-up programs were provided is hampered by the fact that vaccination coverage rather than the uptake in a certain period has been reported in most of these studies. This also applies to a German study based on data from a nationwide telephone survey in girls aged 18–20 y where a coverage of 49% in 2010 has been reported.⁴ Although the HPV vaccination is not recommended by the STIKO for females aged 18 y and older, the proportion of women this age receiving the vaccination in our study was about 12%. In a simulation study, assuming a coverage of 50% the cumulative reduction of cervical cancer cases on the population level over a 100 y period has been estimated between 32% and 12% in girls aged 18 and 26 y, respectively, compared with a reduction by 36.8% when vaccination is administered at the age of 12.²⁵ This finding suggests a lower but still relevant public health impact also if vaccination is given at an older age. In US studies catch-up programs have been reported to be most cost-effective if targeting women up to 18 or 21 y of age.²⁷ These findings can be of practical relevance, as catch-up campaigns for women are currently discussed as an attractive strategy to enhance HPV vaccination coverage in the population.²⁶

Limitations of our study are mainly due to the underlying administrative data used for the analyses. The main limitation concerns the coding of the vaccination in the time period of interest. In the fall of 2007, specific EBM codes for the HPV vaccination were introduced in nearly all federal states. No codes were available in Brandenburg and Hesse, which were therefore not included in the analysis and the study results do therefore not cover all geographical regions in Germany. Nationally uniform vaccination codes should have been introduced in July 2008. In practice, only 10 out of the 16 federal states had implemented the use of the uniform codes by the fall of 2008. Specific codes for females older than 17 y were available only in 4 regions (HH, SH, SN, and NRW). All HPV vaccination codes that were in use during the study period (uniform as well as KV-specific (Regional Association of SHI-Accredited Physicians) codes) were considered for this study. As the HPV vaccine is exclusively administered by certain groups of medical specialists in the outpatient setting in Germany it can be assumed that all vaccinations were captured in the claims data. Results from the Drug Prescription Report indicate that the market share of Gardasil® was about 90% in 2008.²⁸ However, as both existing vaccines are coded

the same, no distinction can be made in our data. Some of the previously published studies have analyzed vaccination coverage or uptake defining vaccinated females as having received the full series of 3 vaccine doses.²⁹ This was not possible in the present study due to the lack of dose-specific codes for the administered HPV vaccines in most of the KV regions. Moreover, the study period of only one year made the consideration of vaccinations received before or after the year 2008 impossible, hampering the possibility to count the number of HPV vaccine doses for each insurant in order to identify complete or incomplete immunization series. However, a recent publication has shown that the percentage of girls in Germany receiving only 1 or 2 doses of the vaccine was relatively low, suggesting that most of the girls are likely to have received the full immunization series even if not within one year.⁴ As no data are available for the time before January 2008, some girls or women might have completed the full immunization series before the start of the study period and were thereby not captured by the present study. However, the vaccine has been recommended in Germany since March 2007 and the completion of the full series according to the vaccination schedule takes at least 6 mo. The number of females completing the series within the year 2007 is therefore not expected to be high. Furthermore, the time lag with which data for uptake analysis was available in this context is a limitation of this study as it obviates the presentation of recent uptake data or the description of vaccine uptake developments. Prompt comprehensive uptake information would be useful as a basis for the near-term development or appropriate adaptation of immunization programs in order to improve vaccination rates.

Since the SHI participating in this study is one of those SHIs that reimburse HPV vaccination also for the ages 18–26 y, the percentage of vaccinated females in the general population in Germany might be slightly lower than presented in our study. Yet, many SHIs offer reimbursement of the vaccine also for females above the recommended age and this overestimation is therefore not expected to be high. For data protection reasons, GePaRD does not contain the exact birthdate but only the birth year; therefore, age groups of one year typically include some girls/women from adjacent age groups at the time of vaccination. The identification of girls who turned 12 y during the study period to exclude previously received uncaptured vaccination was not possible in this context. Furthermore, reasons for the low uptake could not be assessed within this study. Although physicians were trained with regard to the national recommendations concerning the HPV vaccine, we do not have any further information on whether health providers were following the respective recommendations. However, no vaccine shortages or stocking delays that might explain low vaccine uptake in other contexts occurred in this period.

One strength of this study is the size of the study population which includes more than 300 000 insurants from several regions in Germany.^{30,31} This allows precise estimates even within small subgroups (e.g., years of age). Furthermore, due to the administrative character of the data, the results of the present study cannot be affected by volunteer or recall bias, while these limitations might affect information on the vaccination

status from surveys through selective participation or impaired recall.^{5,6}

To the best of the authors' knowledge this is the first study that describes the uptake of the HPV vaccine in females using individual data from an SHI in Germany on a broad regional level and for different age groups based on a large study population. The study reflects the situation shortly after the recommendation of HPV vaccination in Germany and the observed trends by age might be affected by the recent introduction of the vaccine. Vaccination coverage among females in the age just over the recommended age for vaccination (18–20 y) has been reported as 67%³ (at least one dose) and 49%⁴ (3 doses) in Germany in 2010. To improve vaccination rates, public health efforts are necessary. School-based vaccination programs might be one approach in this direction. Alternatively, vaccination at younger ages, when children are vaccinated during routine visits by the pediatrician rather than by the gynecologist might be considered in order to achieve sufficiently high vaccination rates. Beyond that, an alignment of the national recommendations concerning temporary catch-up efforts for females of the ages just over the currently recommended main target age might moreover enhance the vaccination rates in this age group. Furthermore, timely and comprehensive access to and analysis of uptake data would be needed in order to create a basis for prompt public health reactions and efforts to develop or appropriately adapt immunization programs especially for vaccines that are not administered in the context of the obligatory health screening for children.

Disclosure of Potential Conflicts of Interest

E.G. is running and S.H. and K.H. are working for a department that occasionally performs studies for pharmaceutical industries. R.M. and J.H. were employees of this department at the time of study conduct. The pharmaceutical companies include Bayer, Celgene, GlaxoSmithKline, Mundipharma, Novartis, Sanofi-Aventis, Sanofi Pasteur MSD, and STADA. E.G. has been a consultant to Bayer-Schering, Nycomed, GlaxoSmithKline, Schwabe, Teva, and Novartis. E.G. is a member of the German Standing Vaccination Committee (Ständige Impfkommision [STIKO]). R.S.-R. was an employee of Sanofi Pasteur MSD till 31.3.2013. Since 1.4.2013 R.S.-R. is an employee of Bayer Pharma AG.

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Ethical Statements

In Germany, utilization of healthcare insurance data for scientific research is regulated by the code of Social Law (§ 75 SGB X). The Federal Ministry of Health and the contributing SHI

approved the use of the data for this study. Informed consent was not required by law, since the study was based on pseudonymous data.

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